Texas State Board of Pharmacy Laws and Rules Update Webinar FAQs and Troubleshooting Tips

- We will be using the *Chat* box to deliver general information.
 - If you have questions, please use the Q&A box to submit.
- You may send all follow-up questions or handout requests to
- You do not need a microphone just log in to watch and listen.
- We will be doing periodic sound checks before the presentation begins.
- Receiving Credit
- Cocking Credit

 Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 <u>Business</u> days from now

 An email notification will be sent to you when these are available

 Complete these terms to generate your certificate, which can be accessed at any time through your Lifelong

 Learning Account

 Please note: This course is accepted by the Texas State Board of Pharmacy for both general credit and as

 fulfilling the law requirement. However, it is NOT ACPE certified and will not appear in your CPE

 Monitor account.



TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy Law Update

Allison Vordenbaumen Benz, R.Ph., M.S. **Director of Professional Services**

October 12, 2017



Goals

- Review recent changes to pharmacy rules;
- Review Legislation passed by the 2017 Texas Legislature that affects the practice of pharmacy or the Board of Pharmacy; and
- Review the Texas Prescription Monitoring Program.



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TEXAS STATE BOARD OF PHARMACY



Recently Adopted Rules



Pharmacy Technician Registration Requirements

 At the February 2, 2017, meeting, the Board approved the ExCPT examination for pharmacy technician registration beginning September 1, 2017.



Pharmacy Technician Registration Requirements

- Effective Date: March 19, 2017.
- Amends the exam requirements for initial registration to specify that the applicant must have taken and passed <u>a pharmacy</u> technician certification examination <u>approved by the board</u> and have a current certification certificate.
- (Note: Reference to PTCB has been removed.)



TEXAS STATE BOARD OF PHARMACY

Board Rule 295.14

- Dispensing of Opioid Antagonist by Pharmacist
 - Allows a pharmacist to dispense an opioid antagonist under a valid prescription, including:



Board Rule 295.14

- prescription issued by a standing order, to:
 - a person at risk of experiencing an opioidrelated drug overdose; or
 - a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related drug overdose.



TEXAS STATE BOARD OF PHARMACY

Board Rule 295.14

- A prescription dispensed under this section is considered as dispensed for a legitimate medical purpose in the usual course of professional practice.
- A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:



TEXAS STATE BOARD OF PHARMACY

Board Rule 295.14

- dispensing or failing to dispense the opioid antagonist; or
- if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.



Class A Pharmacy Library Requirements

- Library requirements were amended to
 - Add a new reference if the pharmacy dispenses veterinary prescriptions, the pharmacy must have a general reference text on veterinary drugs.



Pharmacy Related Legislation Passed by the 2017 Texas Legislature



The "Sunset" Bill (HB 2561) Effective Date: 9/1/2017



- **Effective Date: 9/1/2017**
- Amends the Pharmacy Act to:
 - Continue TSBP until 8/31/2029;
 - Amend the duties of the Executive Director (ED) to specify that the ED may perform the duties required by the Act or designated by the Board;
 - Remove the requirement that a person be of good moral character to obtain a license or registration;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Amends the Pharmacy Act to:
 - Allow the Board to <u>refuse to renew</u> a license to practice pharmacy <u>for a license holder</u> who is in violation of a Board order;
 - Specifies that TSBP must adopt rules relating to the CE required for pharmacy technicians.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Amends the Pharmacy Act to specify that pharmacy technician CE requirements must include the:
 - Number of hours of CE;
 - Methods for meeting the CE requirements;
 - Approval of CE programs;
 - Reporting completion of CE;
 - Records of completion of CE; and
 - Board audits to ensure compliance.



- Amends the Pharmacy Act to specify that to renew a pharmacy technician registration, the registrant must, before the expiration date of the registration:
 - Pay the renewal fee; and
 - Comply with the continuing education requirements.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Amends the Pharmacy Act to specify that to renew a pharmacy technician registration after a registration has been expired for:
 - 90 days or <, the technician must pay a renewal fee that is equal to 1½ times the renewal fee;
 - > than 90 days, but < 1 year, the technician must pay a renewal fee that is <u>2 times</u> the renewal fee;
 - 1 year or >, the technician may not renew.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

Adds a new section 551.006 to the Pharmacy Act titled <u>"Exclusive</u> <u>Authority"</u> that specifies that <u>a</u> <u>pharmacist has the exclusive authority</u> <u>to determine whether or not to</u> <u>dispense a drug.</u>



- Adds a new section 551.008 to the Pharmacy Act titled: "Prohibition on Rule Violating Sincerely Held Religious Belief" that specifies:
 - All rules or policies adopted by TSBP may not violate the Religious Freedom provisions of the Texas Civil Practice and Remedies Code; and



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

 A person may assert a violation of the religious freedom provisions as an affirmative defense in an administrative hearing or as a claim or defense in a judicial proceeding.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Amends the Pharmacy Act to add the following definitions:
 - "Provider pharmacy" a Class A phcy that provides phcy services through a telepharmacy system at a remote dispensing site.
 - "Remote dispensing site" a location licensed as a telepharmacy that is authorized by a provider phcy through a telepharmacy system to store and dispense Rx drugs/devices including dangerous drugs and controlled substances.



- Adds the following definitions to the Pharmacy Act:
 - "Direct supervision" supervision by a pharmacist who directs the activities of a pharmacist-intern, pharmacy technician, or pharmacy technician trainee to a sufficient degree to ensure the activities are performed accurately, safely, and without risk of harm to patients, as specified by Board rule.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

Amends the Pharmacy Act to allow a Class A or Class C pharmacy to provide pharmacy services, including the dispensing of drugs, through a telepharmacy system at locations separate from the Class A or Class C pharmacy.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- Specifies that Board must adopt rules regarding the use of a telepharmacy system including the locations eligible to be licensed as remote dispensing sites, which must include:
 - Locations in medically underserved areas;
 - Areas with a medically underserved population; and
 - Health professional shortage areas.



- The Board must adopt rules specifying licensing and operating requirements, including a requirement that a:
 - Remote dispensing site license identify the provider pharmacy that will provide pharmacy services at the remote dispensing site;
 - Provider pharmacy be allowed to provide phcy services at no more than 2 remote sites;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The Board must adopt rules that require:
 - A RPh employed by a provider phcy make at least monthly on-site visits to a remote dispensing site or more frequent visits if specified by Board rule;
 - The perpetual inventory of controlled substances at the remote site be <u>reconciled</u> <u>monthly</u> by a RPh employed by the provider pharmacy;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The Board must adopt rules that require:
 - A RPh employed by a provider pharmacy be physically present when providing services requiring the physical presence of the pharmacist, including immunizations;
 - A remote site be staffed by <u>an on-site</u> <u>pharmacy tech under the continuous</u> <u>supervision of a RPh;</u>



- The Board must adopt rules that require:
 - All pharmacy technicians at a remote site be counted when establishing the pharmacist/pharmacy technician ratio of the provider phcy, which, may not exceed 3 pharmacy technicians for each pharmacist;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The Board must adopt rules that require:
 - Before working at a remote site, a pharmacy technician must have:
 - Worked at least 1-year at a retail phcy during the 3-years preceding the date the pharmacy tech begins working at the remote site; and
 - Have completed a Board-approved training <u>program</u> on the proper use of a telepharmacy system;



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The Board must adopt rules that specify that:
 - A pharmacy tech <u>may not perform</u> <u>extemporaneous sterile or nonsterile</u> <u>compounding</u> but may prepare commercially available meds for dispensing, including the reconstitution of powder antibiotics; and
 - Any additional training or practice experience for pharmacy techs at a remote site.



- The bill specifies that a telepharmacy system at a remote dispensing site may not:
 - Dispense CII controlled substances.
 - Be located within 25 miles, by road, of a Class A pharmacy.
 - Except if a Class A pharmacy is established within 25 miles of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The bill specifies that a telepharmacy system located at a remote site in a county with a population of at least 13,000 but not more than 14,000 may not be located within 22 miles by road of a Class A pharmacy.
 - If a Class A pharmacy is established within 22 miles of a currently operating site, the remote site may continue to operate at that location.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

The Act specified that the Board by rule shall require and develop a process for a remote site to apply for a Class A phcy license IF the average number of Rxs dispensed each day the remote dispensing site is open for business is more than 125, as calculated each calendar year.



The bill adds a new Sec. 481.0764 to the Texas Controlled Substances Act (TCSA) titled "Reports of Wholesale Distributors" to require wholesalers to report to TSBP the sale of a controlled substance made by the distributor to a person in this state.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor

The bill amends the TCSA to require pharmacies to send all required information for Schedule II – V prescriptions to the PMP not later than the next business day after the date the prescription is completely filled.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

The bill amends the TCSA to require each regulatory agency that issues a license, to a prescriber to promulgate specific guidelines for prescribers regulated by that agency for the responsible prescribing of opioids, benzodiazepines, barbiturates, or carisoprodol.



- The bill amends the TCSA to specify that after 9/1/2019, a pharmacist or prescriber authorized access the PMP, other than a veterinarian, shall access the PMP for the patient before prescribing or dispensing:
 - Opioids;
 - Benzodiazepines;
 - Barbiturates; or
 - Carisoprodol.



TEXAS STATE BOARD OF PHARMACY

Data from the PMP- FY2017				
Controlled Substance Dispensed	# Rxs Dispensed	% of the 4 Controlled Substances Dispensed	% of ALL Controlled Substances Dispensed	
Barbiturates	192,974	<1%	<1%	
Benzodiazepines	8,308,209	31%	21%	
Carisoprodol	528,543	2%	1%	
Opioids	17,984,222	66%	45%	
Total of Above Controlled Substances Dispensed	27,013,858		<u>68%</u>	
Total of Other Controlled Substance Dispensed	12,405,658		32%	
Grand Total of All Controlled Substance Dispensed	39,419,516			
BARBITURATES, BENZODIAZ REPRESENT <u>68% OF ALL COI</u> DURIN		UBSTANCES E		

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The bill amends the TCSA to specify that a:
 - A dispenser or prescriber may access information of a patient before dispensing or prescribing any controlled substance; and
 - A <u>veterinarian</u> may access the info for Rxs dispensed <u>only for the animals of an owner</u> and may not consider the personal Rx history of the owner.



The bill amends the TCSA to specify that if a prescriber or dispenser violates the law related to the access of the PMP, this action is grounds for disciplinary action by the regulatory agency that issued a license to the person who committed the violation.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The bill amends the TCSA to specify that a prescriber is not subject to the grounds for discipline requirements if the:
 - Patient has been diagnosed with cancer or the patient is receiving hospice care; and
 - Prescriber clearly notes in the Rx that the patient was diagnosed with cancer or is receiving hospice care, as applicable.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The bill amends the TCSA to specify that a <u>dispenser</u> is not subject to the grounds for discipline requirements if:
 - It is clearly noted in the prescription record that the patient has been diagnosed with cancer or is receiving hospice care.



The bill amends the TCSA to specify that a prescriber or dispenser is not subject to the requirements mandatory lookup IF the prescriber or dispenser makes a good faith attempt to comply but is unable to access PMP because of circumstances outside the control of the prescriber or dispenser.



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)

- The new chapter specifies requirements for an individual to donate unused Rx drugs (dangerous drugs only) to a participating provider (health-care facility or pharmacy).



TEXAS STATE BOARD OF PHARMACY

HB 2561 by Rep. Senfronia Thompson/Sen. Van Taylor (cont.)



The bill amends the education code to specify that:

The college shall be known as the Texas A&M University System Health Science Center Irma Lerma Rangel College of Pharmacy, and the primary building in which the school is operated shall be located in Kleberg County and must include "Irma Rangel" in its official name.



Other Pharmacy Related Bills Passed by the Texas Legislature



HB 1178 by Rep. Kuempel/Sen. Hinojosa

- **Effective Date: 9/1/2017.**
- Increases the penalty for stealing a controlled substance to a felony if the:
 - Building in which a controlled substance is stored is a pharmacy, clinic, hospital, or nursing facility; and
 - Person entered or remained concealed in that building with intent to commit a theft of a controlled substance.



TEXAS STATE BOARD OF PHARMACY

HB 1178

by Rep. Kuempel/Sen. Hinojosa (cont.)

Amends the penal code to specify that an offense is a <u>state jail felony</u> if a controlled substance is taken, <u>regardless</u> <u>of the value of the controlled</u> <u>substance stolen.</u>



SB 1633 by Sen. Perry/ Rep. Oliverson

NOTE: These provisions are also contained in the HB 2561

 <u>Effective Date:</u> Takes effect immediately on signature of the Governor. <u>The Board</u> <u>shall adopt rules no later than 1/1/2018.</u>



Texas Prescription Monitoring Program



PMP AWARXE

Go to the PMP Website:

texas.pmpaware.net

OR

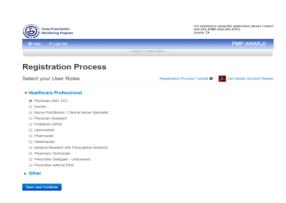
Go to the TSBP Website:

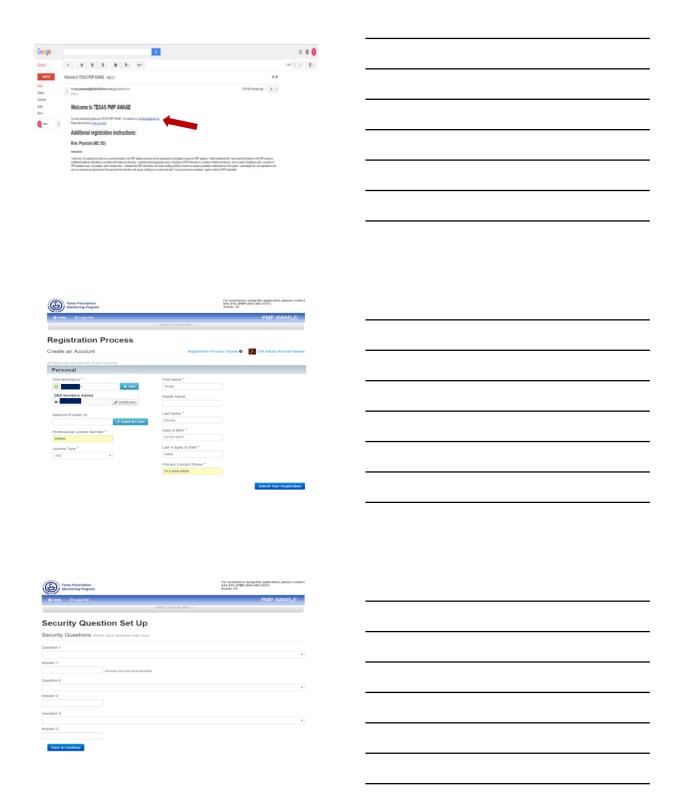
www.pharmacy.texas.gov

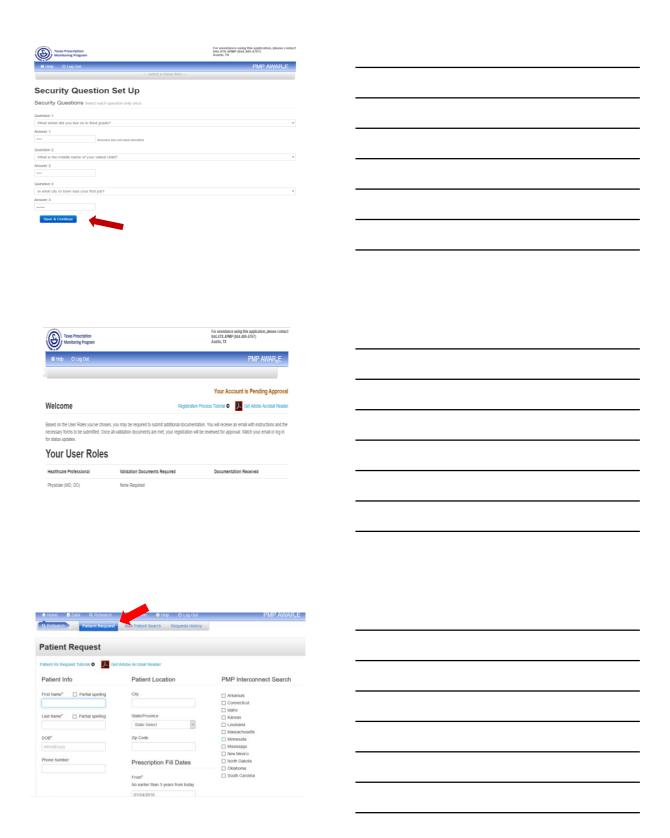


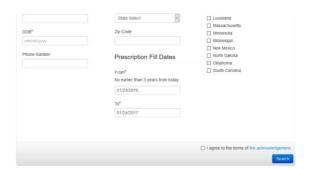


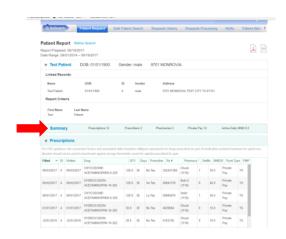














PRESCRIPTION MONITORING PROGRAM FY2017 Quarterly Reports					
	1 st Quarter	2 nd Quarter	3 rd Quarter	4 th Quarter	Year-to- Date
Registered Users	43,227	5,494	4,773	5,148	58,642
Searches	800,041	982,602	1,113,526	1,279,436	4,175,605
Prescriptions Dispensed	10,123,585	10,092,111	9,856,895	9,346,925	39,419,516



Still valid prescription forms!





Texas Prescription Monitoring Program Facebook Page

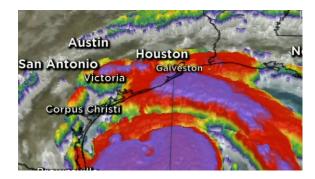


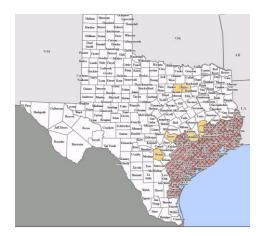
www.facebook.com/TexasPMP/

The Texas PMP Facebook page will offer news and updates specific to the program.

Hurricane Harvey











Hurricane Harvey Statistics

	# Issued
Emergency Temporary Pharmacist Licenses	451
Emergency Remote Pharmacy Licenses	18
Emergency Temporary Pharmacy Technician Registrations	80

	TEXAS STATE BOARD OF PHARMACY
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Final Reminders

- Receiving Credit
 - Look for the quiz and evaluation to be posted in your Lifelong Learning Account 5-7 days from now
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Trouble accessing your Lifelong Learning Account?
Questions about your attendance?
Call the help desk:
1-800-215-0641
Select Option 1

Please note: This course is accepted by the Texas State Board of Pharmacy for both general credit and as fulfilling the law requirement. However, it is NOTACPE certified and will not appear in your CPE Monitor account.



TEXAS STATE BOARD OF PHARMACY

Thank You!

Thank you for your attendance!

If you have additional compliance-related questions, please call the TSBP Compliance Line at 512-305-8070.

For questions about today's presentation, please email us at:

educationcoordinator@pharmacy.texas.gov

